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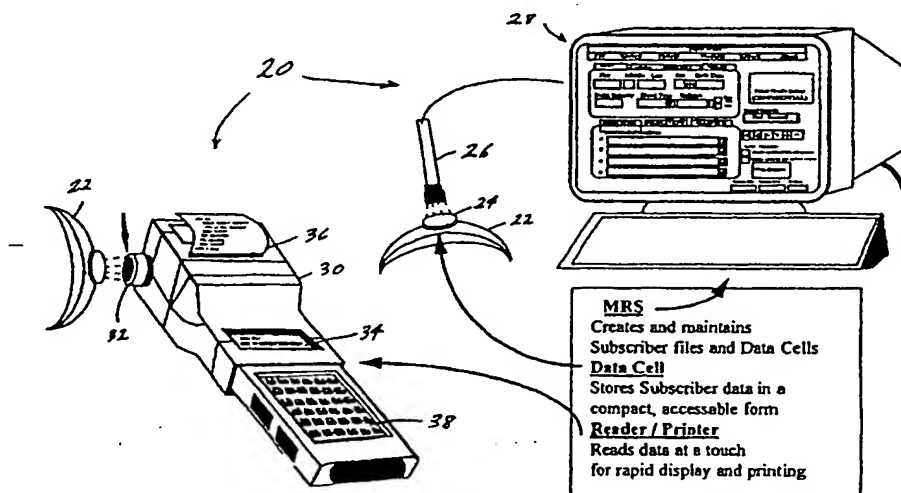
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: MEDICAL INFORMATION RECORD SYSTEM



## (57) Abstract

A medical information record system provides access to medical information of persons in emergency response situations. The system includes a portable data storage device (22) located in a carrier worn by a person. The portable data storage device contains current medical information records specific to the person wearing the device. A handheld reader (30) accesses the medical records contained in the portable data storage device via a probe (32) and a display for displaying the information to medical personnel. A distributed medical record database system (76) operates in conjunction with the reader and portable storage device for managing the personal medical information records. The distributed database system includes a central database location in communication with at least one localized database system location for coordination of medical records on a national scale. The distributed medical record database system includes the capability of creating and managing the personal medical records, and recording the personal medical records on the portable data storage device.

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## MEDICAL INFORMATION RECORD SYSTEM

### FIELD OF THE INVENTION

The present invention relates to medical information record systems, and more particularly, to a medical information record system for providing access to medical  
5 information of persons in emergency response situations.

### BACKGROUND OF THE INVENTION

Emergency response teams often lack critical medical information which may aid in the diagnosis and stabilization of an incapacitated person. The elderly may be especially difficult to treat, often exhibiting the combination of complex medical  
10 conditions and limited communication ability. If the person under treatment is awake and coherent, some of this information may be obtained verbally. However, often the medically-incapacitated person is unconscious or unaware of the relevant medical information.

A number of potential data storage and retrieval systems have been  
15 proposed to address this problem. These include wristwatches with internal storage memory, wristbands with small LCD displays, smart cards, or optical disks. For example, U.S. Patent No. 5,337,290 is directed to a health watch that provides instant access to critical medical data. The health watch is worn on the wrist like a conventional wristwatch, and contains integrated circuit memory which includes data relating to  
20 medical conditions such as vital signs, chronic conditions, allergies, medications, etc. Specifically, in the '290 patent, the small digital wristwatch houses an 8051 microcomputer, memory, and an LCD screen. Buttons on the watch call up specified medical data which is shown on the LCD screen. The electronic circuitry for computing, data storage and data I/O is contained within an Application Specific Integrated  
25 Circuit (ASIC) which is custom-designed for this application in order to meet the very restricted packaging constraints. One drawback to the device of the '290 patent is that it is relatively expensive and thus drives the cost of every device by the cost of the custom ASIC and the required LCD display screen. Additionally, complex keystrokes are required to display the requested data on very limited display screen sizes. The device  
30 also has a limited memory capability and display capacity, requiring the operator to sequence through a number of keystrokes to display all required information.

- 2 -

Another device similar to the '290 patent is shown in U.S. Patent No. 5,012,229 which is directed to a wearable/personal medical information device that includes a memory for storing medical information related to the person wearing the device. The device described in the '229 patent is a flexible wristband and like the  
5 previous patent, it also uses a built-in LCD screen to display pertinent patient personal and/or medical data. The device contains Read Only Memory (ROM) for storing certain data such as medical information, and a Random Access Memory (RAM) for other data which the user may change from time-to-time. The '229 patented device also has a built-in computer and display electronics for accessing and displaying stored data with an  
10 eight character legend display showing the category of data and sixteen character data display showing the specific medical data. Again, like the '290 patent, this patent describes a very expensive solution requiring every wearer to effectively purchase an expensive computer/display.

None of the systems proposed to date adequately address the problem of  
15 acquiring, maintaining, and updating the critical wearer's data. For example, card-based medical data systems require that response teams locate and then access relevant data from a card often located in a wallet or purse. Such a system is described in U.S. Patent No. 4,491,725 which is directed to a medical insurance verification processing system that uses a medical information card to determine a patient's background, medical, and  
20 insurance information. The system uses a card that can be in the form of a "smart card" having an integrated circuit chip which is accessible by means of an appropriate communication device.

Another disadvantage of card and optical disk-based systems is that they suffer from lack of data standards, making it difficult to broadly distribute the technology.  
25 Thus, there is a need for a system that provides response teams with critical medical information that is easily located and accessed.

- 3 -

**SUMMARY OF THE INVENTION**

In view of the foregoing, it is the primary aim of the present invention to provide a medical information record system that provides rapid access to a person's current medical information in emergency response situations.

5 In accomplishing that aim, it is an object of the present invention to provide a distributed medical database system designed to provide rapid access to critical patient medical data for clinics, paramedics, and emergency response teams.

Another object of this invention is to provide a portable data storage module containing current personal medical information that is easily identifiable and  
10 locatable.

A related object of the present invention is to provide a medical information record system that allows emergency medical personnel to rapidly gain access to medical information of incapacitated persons.

An additional object of this invention is to provide a simple, reliable, and  
15 inexpensive memory element, having the memory capacity to maintain all relevant medical data of a person in a compact, dime-sized package.

These and other important aims and objectives are accomplished in accordance with the medical information record system of the present invention. The medical information record system provides access to medical information of persons in  
20 emergency response situations by providing a portable data storage device located in a carrier worn by a person. The portable data storage device contains current medical information specific to the person wearing the data storage device. A handheld reading device accesses the medical information contained in the portable data storage device via a probe and a display for displaying the medical information to medical personnel. The  
25 medical information record system of the present invention also includes a distributed medical record database system that generates and manages personal medical information records. The database system includes a central database system location in communication with at least one localized database system location for coordination of the medical information records on a national scale. The database system also includes  
30 the ability to update personal medical records so that the records contain current personal

- 4 -

medical information, and the ability to record the medical records on the portable data storage device.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

The various aspects of the invention are described in detail below, with  
5 reference to the drawings, in which:

FIG. 1 is a schematic diagram illustrating the components of the medical information record system of the present invention;

FIG. 2 is a closeup view of the portable data storage device of the present invention shown in FIG. 1;

10 FIG. 3A is a block diagram illustrating the process for creating and updating medical records in accordance with the present invention;

FIG. 3B is a block diagram illustrating the process for accessing medical information from the medical information record system of the present invention;

15 FIG. 4 is a block diagram illustrating the components of the portable data storage device shown in FIG. 2;

FIG. 5 is a block diagram illustrating the central and local administration sites of the distributed medical record database system used in the present invention;

FIG. 6 is a functional flow diagram illustrating the process for creating, updating, and verifying medical records in accordance with the present invention;

20 FIG. 7A shows a detailed layout of the main display of the medical information record system of the present invention;

FIG. 7B shows a series of screen captures of various medical-related information used in the medical information record system of the present invention;

25 FIG. 8 is a block diagram further illustrating the details of the handheld reading device for accessing medical information shown in FIG. 1; and

FIG. 9 is a diagram illustrating the keyboard/display of the handheld reading device shown in FIG. 8.

- 5 -

**DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT**

A medical information record system according to the present invention is broadly designated in FIG. 1 by the reference numeral 20. Medical record system 20 is a distributed medical record database system designed to provide rapid access to critical patient medical data for clinics, paramedics, and ER response teams. As shown in FIG. 1, the medical record system 20 of the present invention employs a PC-based medical record system to create, maintain, and update a portable data storage device 22 which contains current medical data and is worn by a patient or subscriber with a critical medical history. In the illustrated embodiment, the portable data storage device 22 is in the form of a bracelet, although the device 22 could be worn by a user in a necklace, badge, wristwatch, etc. Portable data storage device 22 includes a small, compact datacell which contains current medical information specific to the person wearing device 22.

As shown in FIG. 1, medical information important for rapid stabilization and treatment in emergency medical situations, as well as other pertinent medical and personal information, is downloaded to datacell 24 of portable data storage device 22 via a datacell probe 26. Probe 26 is part of a distributed medical record database system 28 for generating, maintaining, and updating personal medical information records. The medical information from datacell 24 can then be accessed by a handheld reading device 30. As shown in FIG. 1, handheld reading device or reader 30 includes a datacell probe 32 for electronically reading the data from datacell 24 in wireless fashion. Reader 30 also includes a data viewing screen 34 so that medical personnel can view a person's medical information after being accessed by probe 32. A printer 36 allows medical personnel to optionally obtain a paper tape printout of the medical data accessed by reader 30. Additionally, reader 30 includes a keyboard 38 for controlling various functions of reader 30.

Referring now to FIG. 2, datacell 24 is shown located on a bracelet 40 and alternatively on a badge 42. The medical information storable in datacell 24 includes information such as subscriber ID number, subscriber name, date of birth, bloodtype, existing medical conditions (diabetes, epilepsy, etc.), current medications, sensitivities or allergies (poison oak, bee, venom, etc.), allergies to medication, emergency contact



- 6 -

phone number, physician contact number, organ donor status, revision level of datacell, date of datacell creation, etc. Candidates for a portable data storage device 22 include elderly patients in a nursing home or managed care living environment, patients with severe allergic sensitivities, epileptic patients, patients with serious heart disease, diabetic patients, etc. As shown in FIG. 2, another application of medical record system 20 includes a medical datacell 24 integrated with an employee badge to allow medical response teams to rapidly access critical data in the event of a medical emergency at the workplace.

FIG. 3A illustrates the process of both creating and updating database records in medical information record system 20 and in associated datacells 24. Those individuals or institutions subscribing to the services provided by medical information record system 20 of the present invention would compile new patient data at step 44 and enter this new patient data into the database associated with medical information record system 20 as denoted at step 46. This information is both stored in a database hard disk location 48 as well as in a datacell itself as shown in step 50. Datacells 24 are marked in an easily-recognizable form and worn on the patient in the form of a bracelet, necklace, ring, etc as mentioned above. The datacell 24 provides a compact, rugged, semi-permanent and readily-accessible data storage medium for medical records.

FIG. 3B illustrates the use of datacell 24 in an emergency response call situation. After responding to an emergency call, the facility medical staff or response team would locate the medical datacell as denoted at step 52, and would access or read the current medical data from datacell 24 with handheld reader 30 as shown in step 54. Handheld reader 30 displays the medical data on the display screen as shown by step 56, and optionally prints a hardcopy of the record as shown in step 58. Additionally, the emergency response team could optionally transmit the pertinent medical data forward to the emergency room staff as indicated at step 60 using facilities equivalent to those used to forward EKG data.

In accordance with the present invention, the key memory technology employed by the present invention for the portable data storage device is a small, rugged, self-contained memory device with built-in power as required for long-term data retention and self-contained data communication circuitry. FIG. 4 illustrates that

- 7 -

datacell 24, in the preferred embodiment, is "dime-sized" (about 16mm or less in diameter and 6mm or less in height) and thus suitable for mounting and comfortably worn in a bracelet, necklace, or some other easily located and accessed carrier. Datacell 24, as shown in the block diagram of FIG. 4, contains a microcircuit non-volatile  
5 memory 62 in the form of either a battery powered Static Random Access Memory (SRAM) or Electrically Programmable Read Only Memory (EPROM). Datacell 24 contains a minimum of 4,096 bits of non-volatile read/write memory with data storage provisions to provide at least a ten year data retention.

Datacell 24 contains all necessary data transfer circuitry 64 for read/write  
10 operations, and a cyclic redundancy check (CRC) circuit 66 for transmission error detection. The device also contains a permanently stored and externally readable digital ID code 68 to uniquely identify the physical device and allow it to be associated with the specific subscriber's medical record. The sealed and durable datacell is designed to be highly resistant to environmental hazards such as dirt, moisture, temperature, and shock.  
15 Data access is via single wire serial data communication and provides a full 4,096 bit transfer in less than 500ms. Datacell 24 also includes a datacell power source 70, memory address/control circuitry 72, and data registers 74. A suitable portable data storage device 22 for purposes of the present invention includes the Dallas Semiconductor 19XX family of Touch Memory devices.

20 As mentioned previously, the medical information record system of the present invention includes a distributed medical record database system for generating, maintaining, and updating personal medical information records. The distributed medical record database system is a database management system hosted on a Windows-based computing platform, and performs the following major functions: (1) creation and  
25 storage of subscriber records on hard disk; (2) display and printing of subscriber records; (3) loading (writing) of datacells; (4) reading and verification of datacells against subscriber files; and (5) updating of subscriber medical files and datacells.

FIG. 5 shows a simplified block diagram of the distributed medical record database system, broadly designated in the drawing by reference numeral 76. System 76  
30 includes both a central administration site 78 and at least one local administration site 80, although it is envisioned that the present invention will include multiple local

- 8 -

administration sites across the country so that medical information records can be coordinated on a national scale. As shown in FIG. 5, each administration site includes a CPU/Memory 82, a display 84, hard disk storage 86, keyboard capability 88, a printer interface 90, and a modem interconnect 92 for communication between sites.

- 5 Additionally, each administration site includes a probe I/O port 94 for downloading of the medical records maintained by the administration sites to datacells 24.

Subscriber medical data files are generated and maintained on the distributed medical record database system 76 using a standard Database Management System (DBMS). Individual subscriber records are maintained with the database records

10 structure and data contents as shown in the following Table 1.

**Table 1 - Subscriber File Structure**

Field ID	Field Name	Data Type	Description	Datacell Bytes
<b>Data Fields</b>				
1	Last Name	Text	Last Name of Subscriber	15
2	First Name	Text	First Name of Subscriber	10
3	Middle Initial	Text	Middle Initial of Subscriber	1
4	Sex	Text	Sex of Subscriber	1
5	Date of Birth	Text	Birthdate of patient	8
6	Social Security #	Text	SSN of Wearer	8
7	Blood Type	Blood Type Code	Code designating subscribers Blood Type	1
8	Religion	Religion Code	Code designating subscriber's religion	1
9	Donor Card Status	Yes/No	Code Indicating Donor Status	1
10	Code	Yes/No	Code Indicating CODE/NO CODE	1

- 9 -

	Field ID	Field Name	Data Type	Description	Datacell Bytes
	11 Physical Address	Street	Text	Physical Address Street	-
5	12 Physical Address	City	Text	Physical Address City	-
	13 Physical Address	State	Text	Physical Address State	-
10	14 Physical Address	Zip Code	Text	Physical Address Zip Code	-
15	15 Mailing Address	Street	Text	Mailing Address Street	-
	16 Mailing Address	City	Text	Mailing Address City	-
20	17 Mailing Address	State	Text	Mailing Address State	-
	18 Mailing Address	Zip Code	Text	Mailing Address Zip Code	-
25	19	EC First Name	Text	First Name of emergency contact	10
	20	EC Last Name	Text	Last Name of emergency contact	15
	21	EC Phone Number	Text	Phone number of emergency contact	10
	22	Physician First Name	Text	First Name of Physician	10
	23	Physician Last Name	Text	Last Name of Physician	15
30	24	Physician Phone Number	Text	Phone number of Physician	10

- 10 -

Field ID	Field Name	Data Type	Description	Datacell Bytes
25	Insurance Carrier	Text	Subscriber's Insurance Carrier	-
26	Policy Number	Text	Subscriber's Policy Number	-
27	Current Medical Condition A	Special Medical Condition Code-A	Code designating Special Medical Condition - A	1
28	Current Medical Condition B	Special Medical Condition Code-B	Code designating Special Medical Condition - B	1
29	Current Medical Condition C	Special Medical Condition Code-C	Code designating Special Medical Condition - C	1
30	Special Medical Condition D	Text	Text describing Special Medical Condition not found in standard table	15
31	Special Medical Condition E	Text	Text describing Special Medical Condition not found in standard table	15
32	Current Medications A	Current Medical Condition Code-A	Text describing prescription medication	1
33	Current Medications B	Current Medical Condition Code-B	Text describing prescription medication	1
34	Current Medications C	Current Medical Condition Code-C	Text describing prescription medication	1
35	Special Medications D	Text	Text describing prescription medication not in the standard medication table	15

- 11 -

Field ID	Field Name	Data Type	Description	Datacell Bytes
36	Special Medications E	Text	Text describing prescription medication not in the standard medication table	15
37	Allergy Field A	Allergy Code-A	Code designating Allergy Type-A	1
38	Allergy Field B	Allergy Code-B	Code designating Allergy Type-B	1
40	Allergy Field C	Allergy Code-C	Code designating Allergy Type-C	1
40	Creation Date	Text	Date Of Record/ Datacell creation	8
41	Revision Date	Text	Date of Record/ Datacell revision	8
41	Revision #	Text	Revision # Of Record/Datacell	1
42	Datacell ROM ID	Text	ROM ID of Subscribers Datacell (This ID is unique to each Datacell and is permanently stored (burned) in ROM at the factory)	0 (This ID is stored as part of the subscriber Database file but is burned into a permanent ROM)

As can be seen, FIG. 6 shows the three primary operating modes of distributed medical record database system 76 of medical record system 20. These three primary operating modes are: (A) file generation and datacell creation, (B) file and datacell updates, and (C) datacell verification. The Create mode (A) is invoked with a new subscriber and results in the creation of both a new record and a new datacell as denoted at step 96. Following the entry of new updated subscriber data at step 98, a file verification process 100 is performed. The subscriber data is then written to the datacell

- 12 -

at step 102, and CRC error-checking is performed at step 104 to ensure that subscriber data has been transferred to the datacell error free. Following successful data transfer as determined at step 106, the datacell ROM ID is read into the system from the permanent, internal datacell ROM at step 108 and stored with the subscriber record at step 110. By this method, there is always a recorded association between the subscriber record and a specific, unique datacell. Following this step, the entire subscriber record is stored in the distributed database system 76 at step 112.

In the Update record mode (B), a file administrator can call up an existing subscriber's file at step 114 by searching for name, social security number, or datacell ID. The file is then updated at step 98, and either a new datacell written, or the original datacell updated with the new subscriber data. In the Verify mode (C), the datacell verification process begins at step 116. At step 118, the datacell is probed and both the datacell ID and the data contents are read in the PC memory for display. CRC error-checking is performed at step 120 and a determination is made as to whether a data transfer error exists as shown in block 122. If a repeated error occurs as shown in block 124, the system declares the datacell as bad at step 126 such that a new datacell is required. The database system is searched by datacell ID at step 128, and if no record is found which matches the datacell ID as determined in step 130, an error message is displayed at step 132 indicating that no record is found. If a record is found but there is a mismatch in the data fields as determined by step 134, a data error message is displayed at step 136 indicating that the datacell is invalid. In this situation, the data has either been corrupted or the subscriber database record updated without a corresponding datacell written. In this case, a new datacell must be written from the latest subscriber record. If a record is found with matching data fields, the subscriber data is displayed and a record match message 138 is displayed to the operator.

FIGS. 7A and 7B illustrate representative data screens for the medical information record system 20 according to the present invention. FIG. 7A shows the main screen of system 20 allowing selection of each of the major record field categories. FIG. 7B shows each of the individual data entry screen for seven specific data types. These include subscriber/patient basic information screen 140, address information screen 142, emergency contact and physician information screen 144, insurance

- 13 -

information screen 146, relevant medical conditions information screen 148, special medications information screen 150, and allergies information screen 152. Pull-down menus are used to select from standard data categories, and fill-in screens are used to allow for entry of non-standard conditions.

5           FIG. 8 provides further details of the handheld reader 30 shown in FIG. 1. More specifically, FIG. 8 is a simplified block diagram illustrating the main components of handheld reader 30 which include a display 34, CPU/Memory 154, communications interface 156, keypad 38, printer interface 36, and power source 158. Additionally, reader 30 includes a probe I/O port 160 for the data probe 32. As shown in FIG. 8,  
10       communications interface 156 can optionally communicate with a remote data terminal 162 to provide access to database system 76 for real-time record verification or to a local hospital or emergency medical center for data transmission for emergency room notification. Thus, remote data terminal 162 can include a satellite link 164, an RF datalink 166, and/or a cellular datalink 168. This capability allows the present invention  
15       to be used, for example, by emergency medical personnel to communicate with an organ donor network to aid in the rapid identification of candidate organ recipients.

          FIG. 9 provides further details of the keyboard and display of reader 30. When the operator probes a datacell, reader 30 immediately responds with a display of the subscriber name, donor status, bloodtype, social security number, emergency contacts,  
20       etc. A single keystroke brings up a display of current medical conditions, existing medications, and known allergies. Both horizontal and vertical scrolling is used to maximize utilization of the LCD screen. This scrolling is performed with scroll arrow keys 170 on keyboard 38. The down arrow on keyboard 38 allows the operator to scroll down the retrieved medical record selecting four of seven lines of medical data for  
25       review. If the data displayed on the screen is too long for the 20 character screen, the reader will automatically scroll side-to-side to allow the operator to view the entire line content. The left direction arrow key stops side-to-side scrolling and the right direction arrow key restarts scrolling. The "EXE" button allows the operator to view the first of three medical screens, i.e., conditions, medications, allergies. The "EXE" button is  
30       pressed to view each screen. If a hardcopy printout of the medical data is desired, the operator presses the "MODE" button to start the print function.



- 14 -

As is evident from the foregoing description, the medical information record system of the present invention provides rapid access to critical patient medical data for paramedics, ER response teams, and other medical personnel. The invention utilizes small, compact, portable data storage devices worn by patients with critical medical histories and contain current medical data important for rapid stabilization and treatment of an emergency medical condition. The present invention also utilizes a distributed medical record database system to establish, maintain, and update patient records and datacells for nationwide coordination and rapid update of patient records.

- 15 -

WE CLAIM:

1. A medical information record system for providing access to medical information of persons in emergency response situations, the medical information system comprising: a portable data storage device located in a carrier worn by a person, the  
5 portable data storage device containing current personal medical records of medical information specific to the person wearing the data storage device; a handheld reading device for accessing the personal medical records contained in the portable data storage device, the handheld reading device including probe means for accessing the medical records, and means for displaying the medical records on the handheld reading device to  
10 medical personnel; and a distributed medical record database system for managing the personal medical records, said database system including a central database system location in communication with at least one localized database system location for coordination of the medical records on a national scale, the distributed medical record database system including means for creating and managing the personal medical records,  
15 and means for recording the personal medical records on the portable data storage device.
2. The medical information record system as defined in claim 1 wherein the portable data storage device comprises a self-contained semiconductor memory device.
3. The medical information record system as defined in claim 2 wherein  
20 the carrier comprises a bracelet, necklace, badge, or other easily located and accessible carrier.
4. The medical information record system as defined in claim 2 wherein the portable data storage device includes a permanently stored and externally readable identification number to provide a permanent association between a person and a specific  
25 storage device.
5. The medical information record system as defined in claim 2 wherein the portable data storage device includes data transfer circuitry for read/write operations.
6. The medical information record system as defined in claim 5 wherein the portable data storage device includes cyclic redundancy check circuitry for  
30 transmission error detection.

- 16 -

7. The medical information record system as defined in claim 1 wherein the handheld reading device includes communication means for communicating a person's medical records accessed from the portable data storage device to a medical facility.

5 8. The medical information record system as defined in claim 7 wherein the communication means also communicates with the distributed medical record database system to provide substantially instantaneous verification of a person's medical records.

9. The medical information record system as defined in claim 1 wherein  
10 the probe means accesses the medical information contained in the portable data storage device via wireless communication.

10. The medical information record system as defined in claim 1 wherein the means for displaying of the handheld reading device comprises an LCD screen.

11. The medical information record system as defined in claim 10 wherein  
15 the means for displaying of the handheld reading device further comprises a printer for printing a hardcopy of the medical information accessed from the portable data storage device.

12. The medical information record system as defined in claim 1 wherein the means for creating and managing includes means for updating the personal medical  
20 records so that said records contain current personal medical information.

13. The medical information record system as defined in claim 1 wherein the distributed medical record database system further includes means for verifying the contents of the portable data storage device to ensure the accuracy and integrity of the personal medical records stored in the portable data storage device.

25 14. The medical information record system as defined in claim 1 wherein the personal medical records comprise data on a person's name, date of birth, address, blood type, existing medical conditions, medications, sensitivities or allergies, emergency contact phone number, physician contact number, organ donor status, and identification number.

- 17 -

15. A method of maintaining personal medical information records to provide access to medical information of persons in emergency response situations, the method comprising: generating and storing personal medical records on a distributed medical record database system; recording the personal medical records on portable data storage devices; providing a person with a portable data storage device located in a carrier worn by the person, the portable data storage device containing personal medical records specific to the person; updating the personal medical records as necessary in the distributed medical record database system and in the portable data storage device so that said records contain current personal medical information; and accessing the personal medical records from the portable data storage device worn by the person with a handheld reading device to display the personal medical records to medical personnel in emergency response situations.

16. The method as defined in claim 15 further comprising the step of: providing a central medical record database system location and at least one localized medical record database system location for coordination of the personal medical records on a national scale.

17. The method as defined in claim 15 further comprising the step of: verifying the contents of the portable data storage device to ensure the accuracy and integrity of the personal medical records stored in the portable data storage device.

18. The method as defined in claim 15 further comprising the step of: communicating the personal medical records accessed from the portable data storage device to a medical facility.

19. The method as defined in claim 15 wherein the portable data storage device comprises a self-contained semiconductor memory device.

20. The method as defined in claim 15 wherein the carrier comprises a bracelet, necklace, badge, or other easily located and accessible carrier.

21. The method as defined in claim 15 wherein the portable data storage device includes a permanently stored and externally readable identification number to provide a permanent association between a person and a specific storage device.

22. The method as defined in claim 15 wherein the personal medical records comprise data on a person's name, date of birth, address, blood type, existing medical

- 18 -

conditions, medications, sensitivities or allergies, emergency contact phone number, physician contact number, organ donor status, and identification number.

23. A medical information record system for providing access to medical information of persons in emergency response situations, the medical information system comprising: a portable data storage device located in a carrier worn by a person, the portable data storage device containing current personal medical records of medical information specific to the person wearing the data storage device; a handheld reading device for accessing the personal medical records contained in the portable data storage device, the handheld reading device including probe means for accessing the medical records, and means for displaying the medical records on the handheld reading device to medical personnel; and a distributed medical record database system for generating, maintaining, and updating the personal medical records, said database system including a central database system location in communication with at least one localized database system location for coordination of the medical records on a national scale, the distributed medical record database system including means for creating and storing the personal medical records, means for updating the personal medical records so that said records contain current personal medical information, means for recording the personal medical records on the portable data storage device, and means for verifying the contents of the portable data storage device to ensure the accuracy and integrity of the personal medical records stored in the portable data storage device.

24. The medical information record system as defined in claim 23 wherein the handheld reading device includes communication means for communicating a person's medical records accessed from the portable data storage device to a medical facility.

25. The medical information record system as defined in claim 23 wherein the portable data storage device comprises a self-contained semiconductor memory device.

26. The medical information record system as defined in claim 25 wherein the carrier comprises a bracelet, necklacc, badge, or other easily located and accessible carrier.

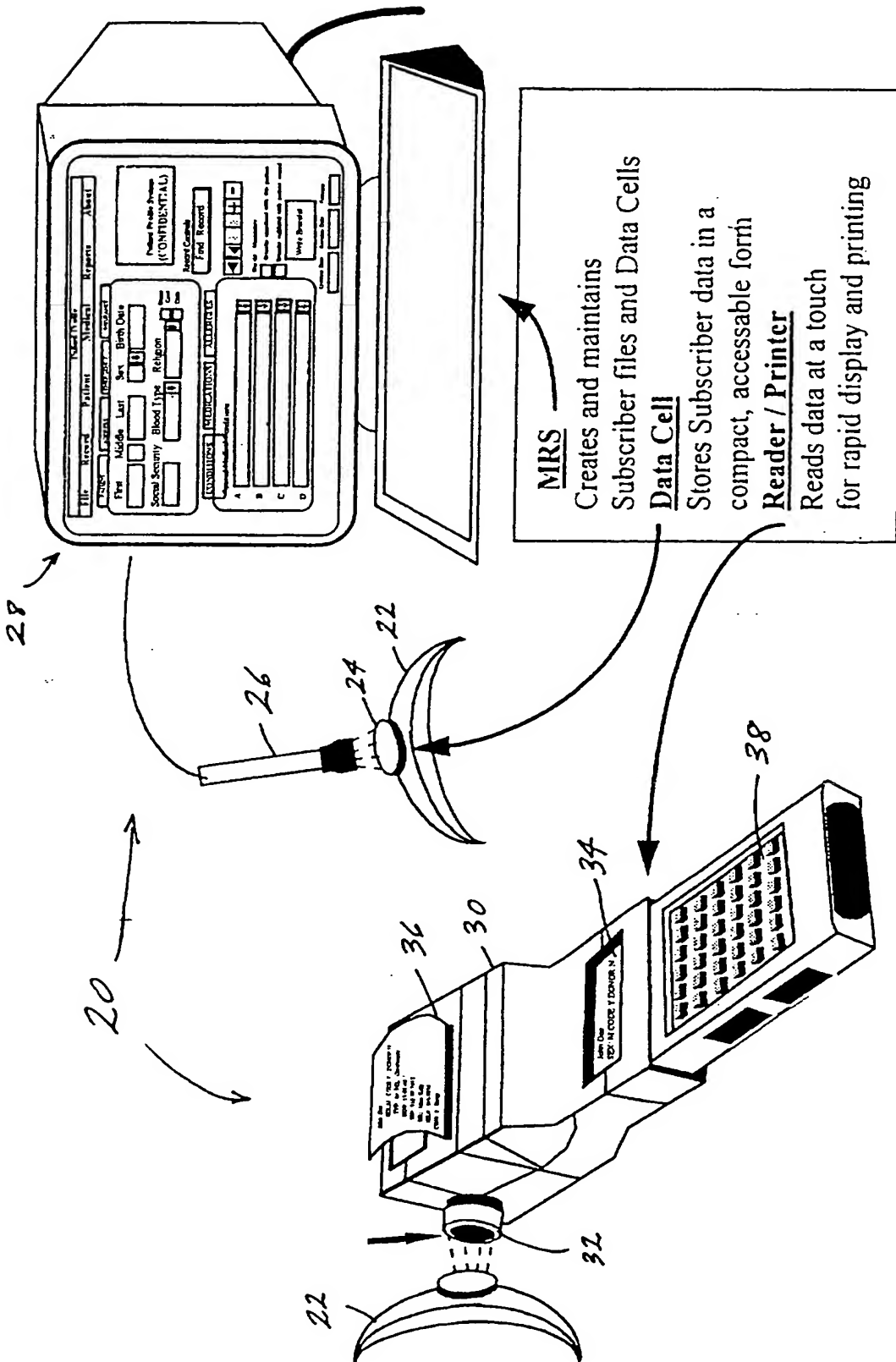


Fig.1

2/10

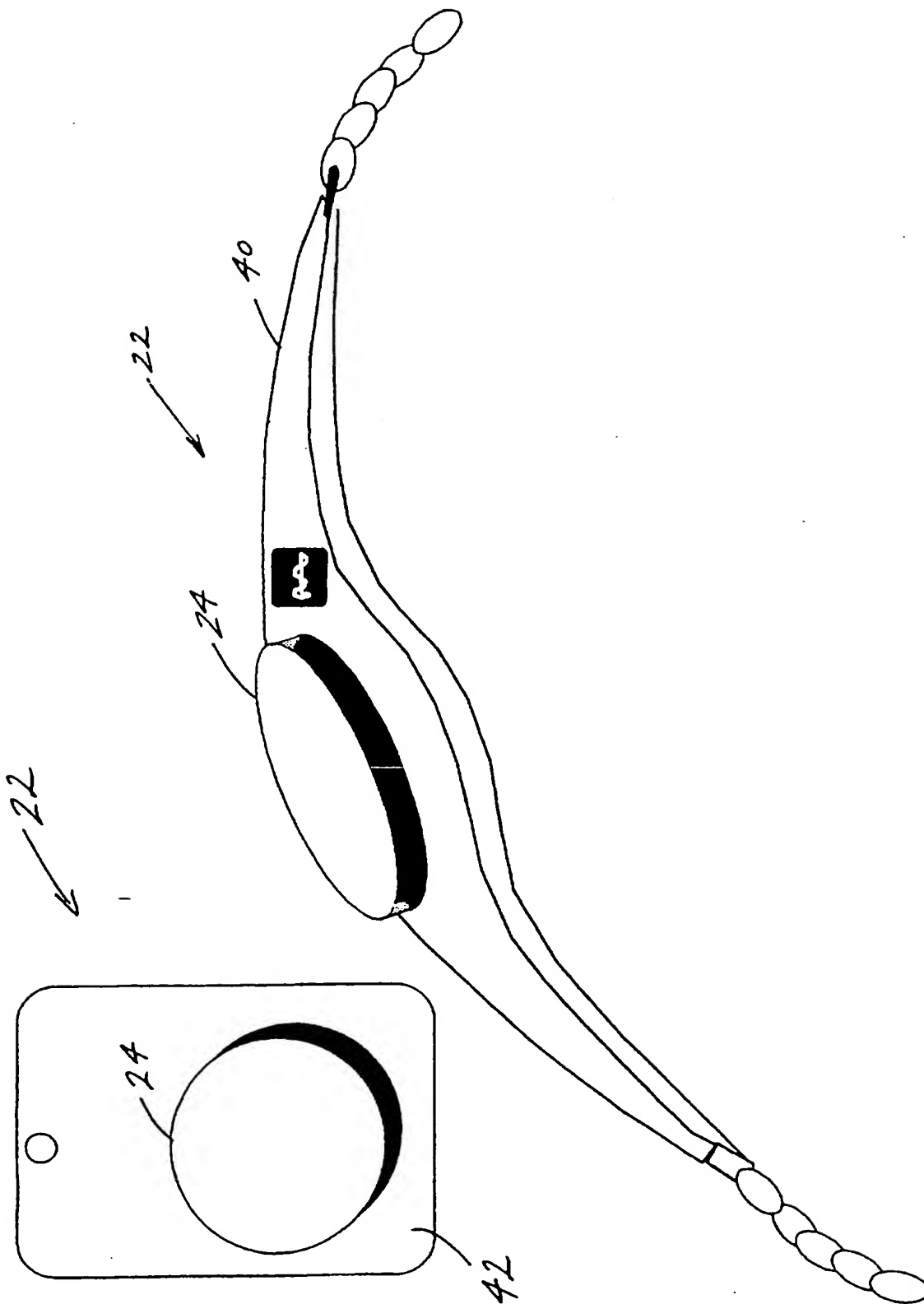


Fig. 2

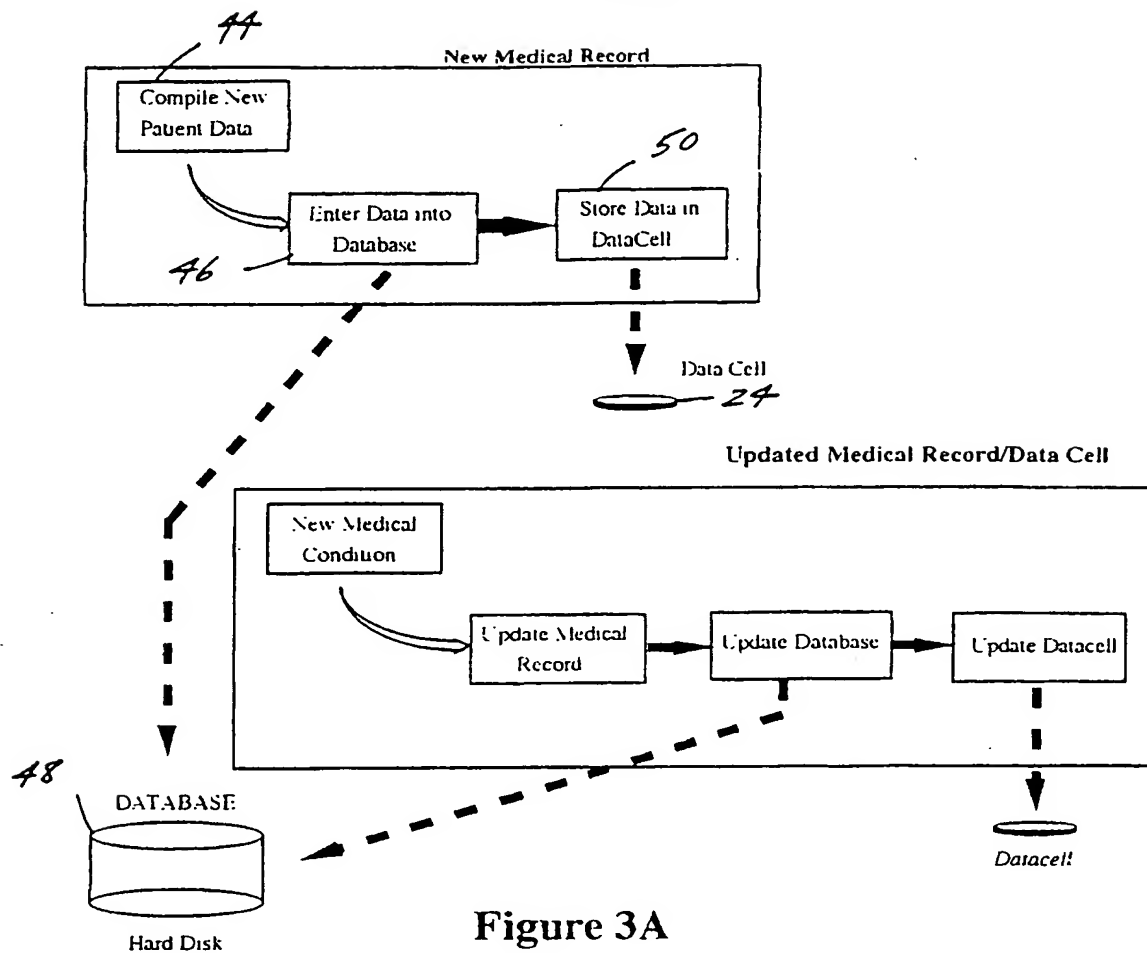


Figure 3A

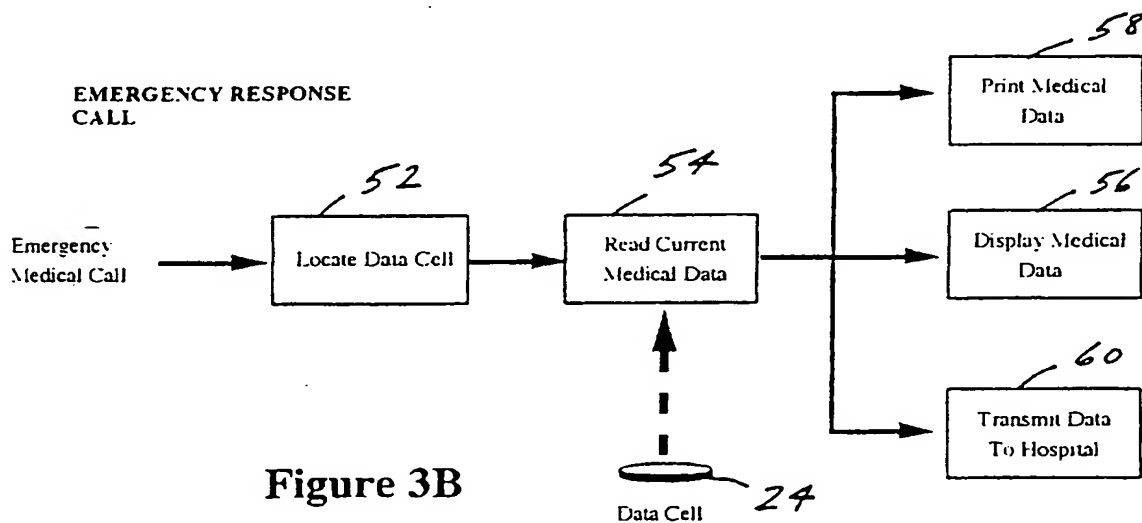
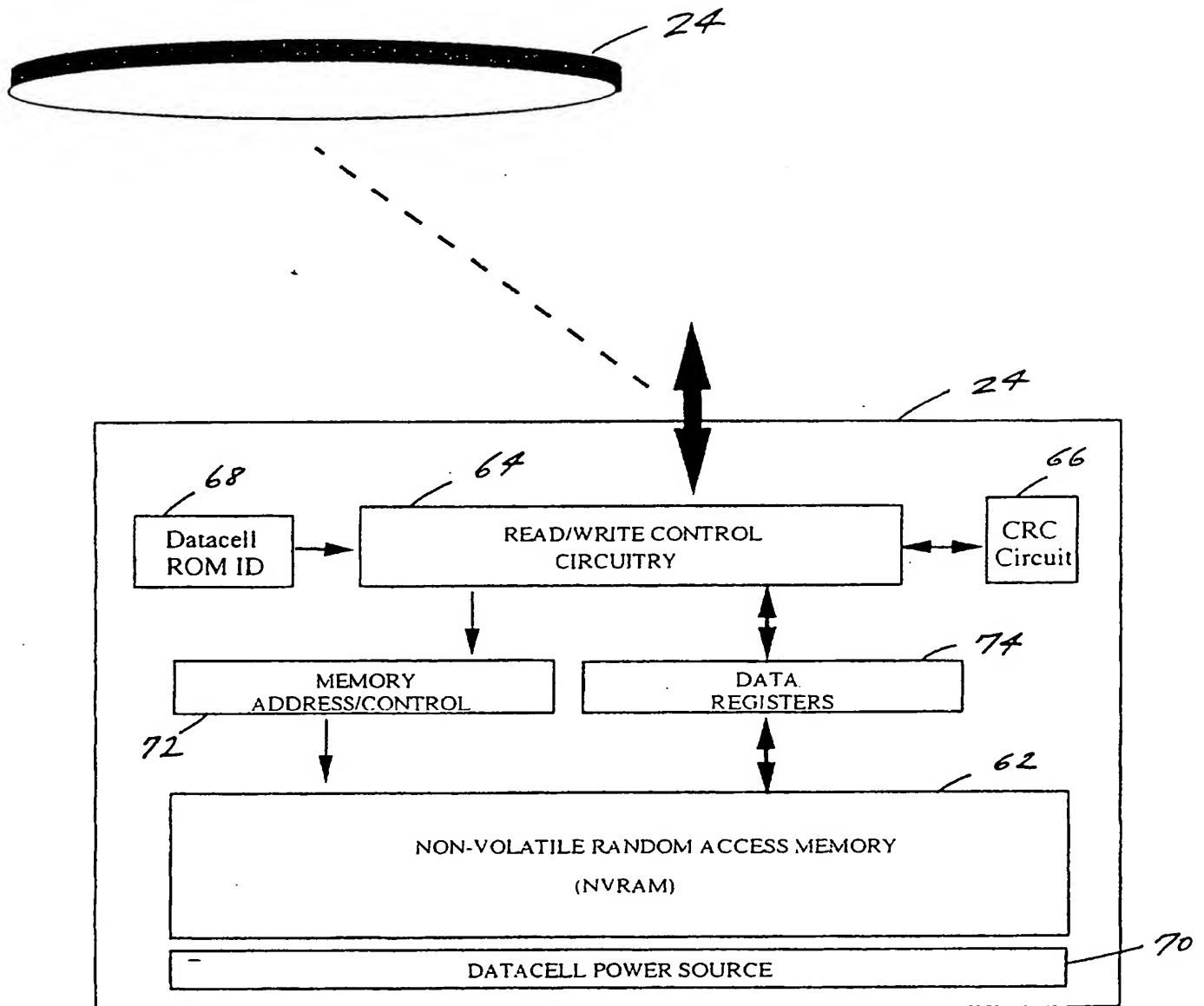
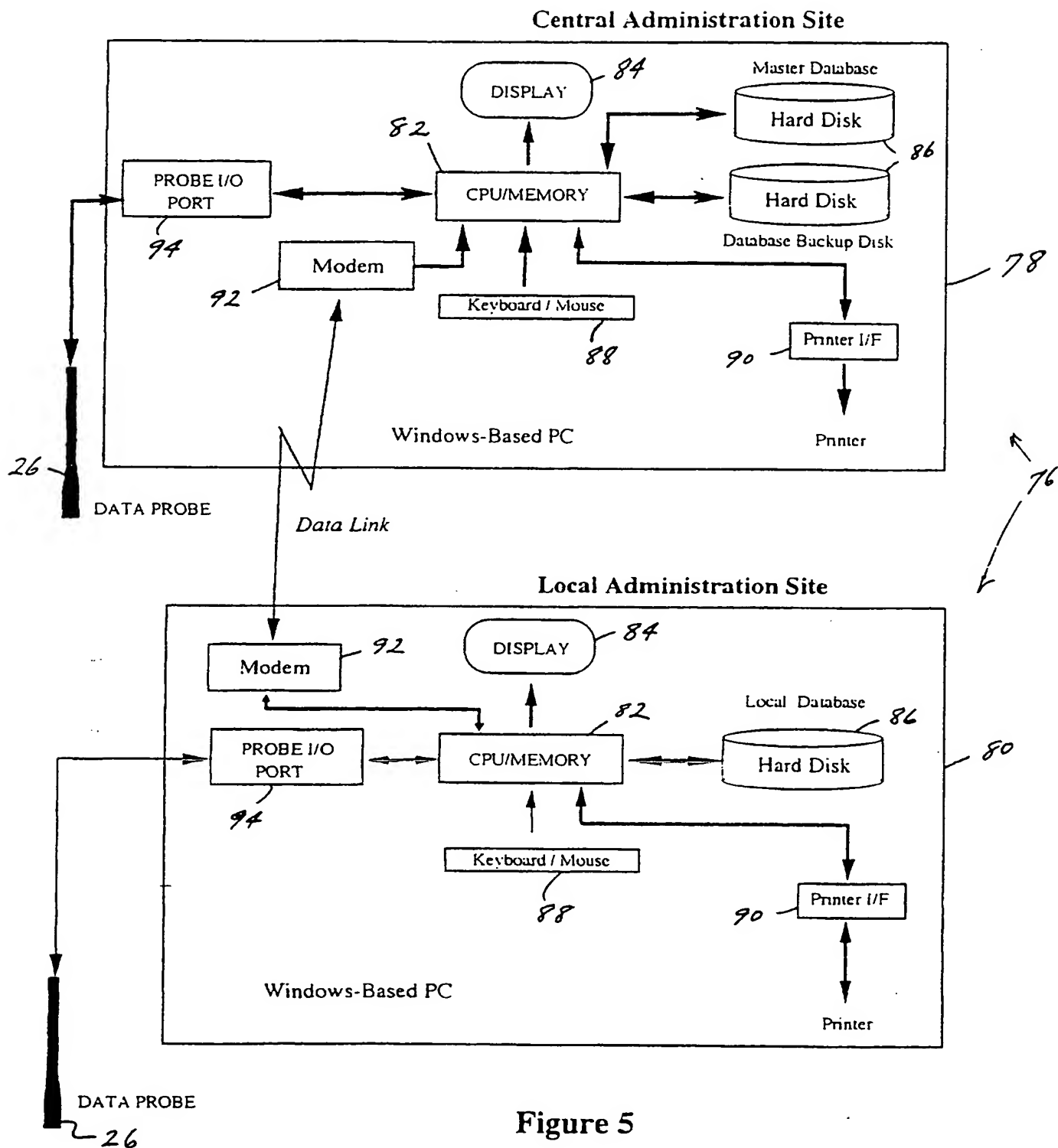


Figure 3B



4/10

**Figure 4**



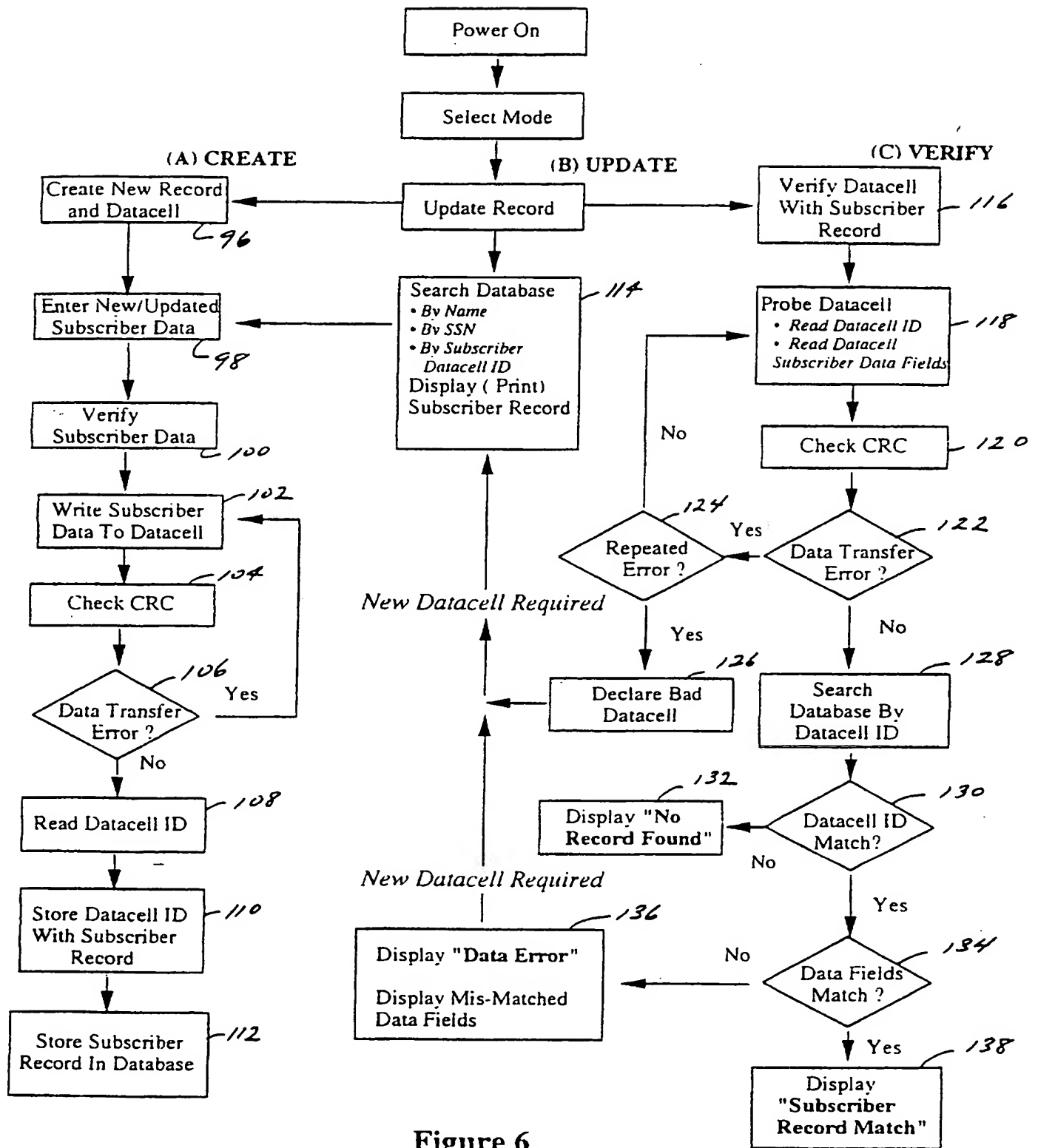


Figure 6

7/10

← 28

File Record Patient Medical Reports About

Patient ADDRESS EMERGENCY INSURANCE

First Middle Last Sex Birth Date

Social Security Blood Type Religion

Special Medical Conditions

A B C D

CONDITIONS MEDICATIONS ALLERGIES

Find Record

Record Controls

Bracelet Maintenance

Write Bracelet

Creation Date Revision Date Revision

Fig: 7A

8/10

**Patient basic information**

**PATIENT**

First  Middle  Last  Sex  Birth Date  Day  Month  Year

Social Security  Blood Type  Religion  Deny Card  DNR

**Address information**

**ADDRESS**

Street  City  State  Zip

Mail Address  City  State  Zip

**Emergency Contact and physician information**

**EMERGENCY**

Emergency Contact First  Last  Phone

Physician First  Last  Phone

**Insurance information**

**INSURANCE**

Insurance  Insurance Company  Policy Number

Insurance  Insurance Company  Policy Number

**Medical Conditions information**

**CONDITIONS**

Special Medical Conditions

A  B  C

Special Medical Conditions

**Special Medications information**

**MEDICATIONS**

Current Medications

A  B  C

Special Medication A

Special Medication B

**Screen #7 Allergies information**

**ALLERGIES**

Allergies

A  B  C

Fig. 7B

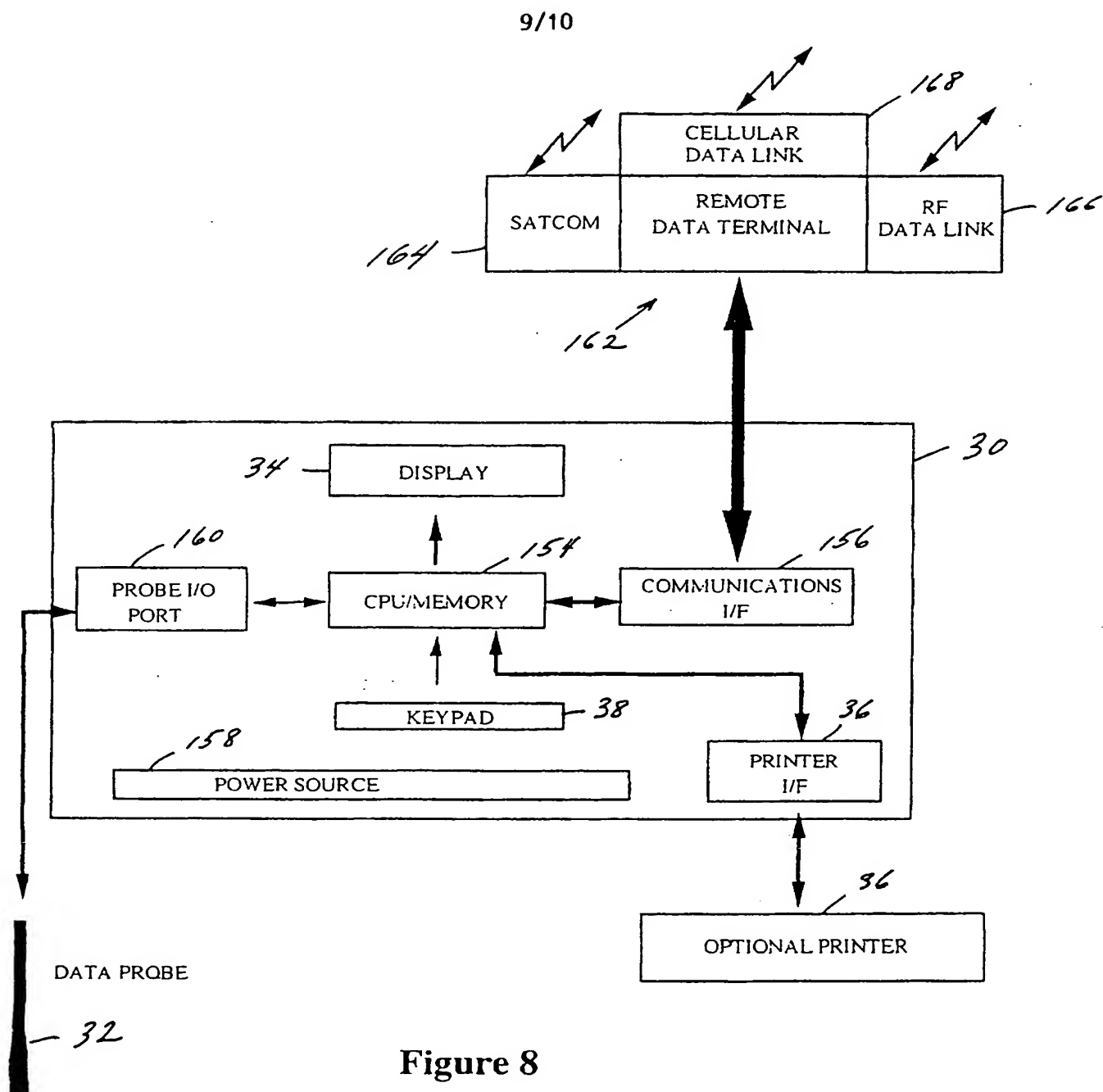


Figure 8

Reader Keyboard

170

38

Name: John Doe Code: Y Don: Y Blo: 0+ DOB: 10-28-46																																	
Clear	Mode	↓	↑	←	→	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	Space	DEL

Fig. 9

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 96/20398

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61B5/117

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 916 441 A (P.P. GOMBRICH) 10 April 1990	1-5
X	see column 1, line 47 - column 3, line 2	7-10
X	see column 4, line 38 - column 7, line 27	12-26
	---	
X	WO 94 06105 A (LIPOMATRIX, INC.) 17 March 1994	1-5, 7-9, 12-17
X	see page 3, line 30 - page 4, line 36	19-24, 26
	see page 5, line 21 - page 6, line 23	
	---	
A	WO 94 04094 A (LIPOMATRIX, INC.) 3 March 1994	1-4, 7-9, 14-16
A	see page 3, line 1 - page 4, line 5	19-23
A	see page 6, line 1 - page 7, line 3	25, 26
	---	
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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- \* "&" document member of the same patent family

Date of the actual completion of the international search

9 May 1997

Date of mailing of the international search report

20.05.97

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Rieb, K.D.



# INTERNATIONAL SEARCH REPORT

Internat. Application No.  
PCT/US 96/20398

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 93 01574 A (L. RUSSEK) 21 January 1993	1-5
A	see page 10, line 3 - page 12, line 23	7-10, 14
A	see page 16, line 14 - page 19, line 17	15, 19-23
A	see page 24, line 22 - page 27, line 2	19-23
	see page 34, line 4 - page 36, line 16	
	-----	

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 96/20398

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4916441 A	10-04-90	NONE	
WO 9406105 A	17-03-94	AU 671859 B AU 4998493 A CA 2142993 A EP 0657056 A JP 8507698 T	12-09-96 29-03-94 17-03-94 14-06-95 20-08-96
WO 9404094 A	03-03-94	US 5300120 A AU 674022 B AU 5003093 A CA 2142995 A EP 0703760 A JP 8501956 T	05-04-94 05-12-96 15-03-94 03-03-94 03-04-96 05-03-96
WO 9301574 A	21-01-93	US 5319355 A EP 0548340 A JP 6502270 T US 5534851 A	07-06-94 30-06-93 10-03-94 09-07-96